

requested.

### **Requirement For Restriction Under 35 U.S.C. § 121**

In the restriction issued October 1, 2002, the pending claims were alleged to describe the following independent and district inventions:

I. Claims 1-3, drawn to a method of modulating phosphate homeostasis in a subject comprising altering the activity of a polypeptide encoded by FRP-4, classifiable in class 514, subclass 2; and

II. Claim 4, drawn to method of modulating renal phosphate transport in a subject comprising altering the activity of a polypeptide encoded by FRP-4, classifiable in class 514, subclass 2 ; and

III. Claim 5, drawn to a method of reducing phosphate re-absorption in a subject comprising delivering a FRP-4 protein, classifiable in class 514, subclass 2; and

IV. Claim 6, drawn to a method of reducing phosphate re-absorption in a subject comprising delivering a polynucleotide encoding a FRP-4 protein, classifiable in class 514, subclass 44; and

V. Claims 7-14, drawn to methods of screening for candidate therapeutic agents that modulate the expression and biological activity of FRP-4, classifiable in 435, subclass 4.

Applicants' undersigned attorney, on behalf of Applicants, hereby elects with traverse to prosecute the invention of Group III, claim 5. Applicants expressly reserve the right under 35 U.S.C. § 121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application, or an application claiming the benefit of this application under 35 U.S.C. § 120.

Applicant also respectfully traverses the grounds for restriction and requests reconsideration and withdrawal of the restriction among Groups I to III, claims 1 to 5. There are two criteria for a proper requirement for restriction, namely, (1) the inventions must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction is not required. Under M.P.E.P. § 808, the Examiner must examine the subject application on the

merits even though it includes claims to distinct inventions, if the search and examination of the application can be made without serious burden. Applicants maintain that the inventions of claims 1 to 5 are not independent or distinct as each claim in Groups I to III relates to the regulation of the FRP-4 protein.

Applicants further maintain that restriction among claims 1 to 5 is improper. First, it would not be a serious burden on the Examiner to search and examine the inventions of Groups I, II and III because each requires the use of FRP-4. Applicants further point out that the methods of claims 1 to 5 in each of the claims of Groups I, II and III are related in function since each relates to modulating phosphate absorption and re-adsorption. Further, pursuant to MPEP § 802.1, "independent (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect . . ." Clearly, there is a disclosed relationship between the methods of Groups I, II and III. (See above).

Finally, a search of the inventions of Groups I through III would not impose a serious burden on the Examiner as each group was classifiable in class 514, subclass 2.

In the event the Office maintains the requirement for restriction among the claims of Groups I to III, Applicants' undersigned attorney respectfully requests that the restriction be made final and the procedure of M.P.E.P. § 821.01 be made of record.

#### **Change of Firm Name**

The undersigned attorneys' advises the office of a change in firm name to Bingham McCutchen, LLP.

#### **Supplemental IDS**

Attached hereto is a Supplemental IDS for consideration and entry into the application file. Applicant also respectfully requests that the references filed with the Office on January 28, 2002 and July 26, 2001, be made of record.

### III. CONCLUSION

No additional fee is deemed necessary in connection with the filing of this Response. However, if the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-2518**, referencing billing number 19442-7201. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Should a telephone advance prosecution of the subject application, the Examiner is invited to contact the undersigned at (650) 849-4950.

DATE: January 17, 2003

Respectfully submitted,

By: Antoinette F. Konski  
Antoinette F. Konski  
Registration No.: 34,202

Bingham McCutchen LLP  
*Formerly McCutchen Doyle Brown and Enersen LLP*  
Three Embarcadero Center, Suite 1800  
San Francisco, California 94111  
Telephone: (650) 849-4950  
Telefax: (650) 849-4800

## VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please add the following new claims:

15. (New) The method of claim 5, wherein the FRP-4 protein has the amino acid sequence of SEQ ID NO: 2.
16. (New) The method of claim 5, wherein the effective amount of the FRP-4 protein is delivered as a polynucleotide that encodes the FRP-4 protein.
17. (New) The method of claim 16, wherein the polynucleotide comprises a polynucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.
18. (New) The method of claim 16, wherein the polynucleotide that encodes the amino acid sequence of SEQ ID NO:2 comprises the polynucleotide sequence of SEQ ID NO:1.
19. (New) The method of claim 17, wherein the polynucleotide is delivered in a gene delivery vehicle.
20. (New) The method of claim 18, wherein the polynucleotide is delivered in a gene delivery vehicle.